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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/308,237      | 05/21/1999  | HIDENORI OHKI        | 0018-1052-0P        | 5890             |

7590 06/26/2002

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/308,237

Applicant(s)

Ohki et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 22, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 47-67 is/are pending in the application.
- 4a) Of the above, claim(s) 48-54 and 56-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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## DETAILED ACTION

### *Status of Claims*

1. ~~Amendment filed 4/22/02 is acknowledged. All previously pending claims,~~ claims 18-46 and replaced with new claims 47-67. Claims 47-67 are pending. As the claims drawn to products remain to stand rejected, claims 64-67, drawn to methods of making and using, remain withdrawn from consideration, as being drawn to previously non-elected groups<sup>1</sup>.

2. As per election of species, as the species addressed in the previous Office action (both the species under art rejection, and species indicated as free of prior art) are no longer claimed, the examination was extended to species where R<sub>1</sub> is benzoyl substituted with phenyl having phenyl having pentyloxy. Claims 47,55 read on thus elected species. Claims 48-54, 56-63 are withdrawn from consideration and are not addressed in art rejections as drawn to non-elected species. A cursory look at the claims, however, revealed that some of the claims have antecedent basis problems (and, possibly, new matter problems) - see, e.g., claim 49, third compound, and claim 61.

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<sup>1</sup>As indicated in the previous Office action, a cursory look at claims drawn to method of use indicated that the claims 44-46 will be subject of the scope of enablement rejection as the only experimental data present in the specification (p. 30-32) demonstrate effect on only two microorganisms, *Candida* and *Pneumocystis*.

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***Claim Rejections - 35 USC § 103***

3. Claims 47,55 are rejected under 35 U.S.C. 103(a) as anticipated by Ohki et al ( WO 96/11210)

Ohki et al teach cyclic peptides of formula 1 which have antifungal activity and pharmaceutical compositions thereof. Radical R1 in the referenced compounds (which corresponds to R1 in the claimed compounds) can be benzoyl substituted with phenyl having phenyl having butyloxy. See example 46, p. 173. The only difference of the referenced compound from the instantly claimed compounds wherein R1 is benzoyl substituted with phenyl having phenyl having pentyloxy is difference in one CH<sub>2</sub>-group in alkoxy radical. The claimed and referenced compounds are homologs. Within the context of chemistry, homologs differing in one CH<sub>2</sub> group are similar in the physical properties, i.e., structurally, and because of their structural similarity, it is generally predictive that their chemical properties will be similar. Because the adjacent homologs would be expected to have similar physical and chemical properties, a high degree of predictability in producing a compound having the same physical and chemical properties would be expected between adjacent homologs in a large compound. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the preferred compounds of WO

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96/11210 such that butyl group in alkoxy radical is replaced by pentyl group. Since one of ordinary skill in the art of general chemistry would have expected that such modifications would not change the properties of a compound in a significant way, one of ordinary skill in the art would have been motivated to make such a modification so as to obtain another preferred compound with the activity disclosed in WO 96/11210.

4. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**MICHAEL BORIN, Ph.D.**  
**PRIMARY EXAMINER**



June 25, 2002

mlb